



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Addressing Inadequate Information on Important Health Factors in Pharmacoepidemiology
Studies Relying on Healthcare Databases; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored by FDA and the University of Maryland Center for Excellence in Regulatory Science and Innovation, entitled “Methodological Considerations to Address Unmeasured Information About Important Health Factors in Pharmacoepidemiology Studies that Rely on Electronic Healthcare Databases to Evaluate the Safety of Regulated Pharmaceutical Products in the Postapproval Setting.” The purpose of the public workshop is to engage in constructive dialogue among regulators, academicians, pharmaceutical industry, clinicians, other stakeholders and the general public on potential strategies to improve availability of information on important health factors in pharmacoepidemiology studies that rely on electronic healthcare databases to evaluate the safety of pharmaceutical products in the postapproval setting. Electronic healthcare databases are increasingly being used in the postapproval assessment of the safety profile of pharmaceutical drug products.

Date and Time: The public workshop will be held on May 4, 2015, 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Contact Person: Leslie Wheelock, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4345, Silver Spring, MD, 301-796-4580, FAX: 301-847-8106, leslie.wheelock@fda.hhs.gov

Registration: Submit your online registration information (including name, title, firm name, address, telephone and fax numbers) by April 30, 2015, at: <http://www.pharmacy.umaryland.edu/centers/cersievents/biasinbigdata/>. There is no registration fee for University of Maryland faculty, students, and staff, University of Maryland Center for Excellence in Regulatory Science and Innovation Industrial Consortia Members, and Federal Government employees. There is a \$50.00 registration fee for all other participants. Early registration is recommended because seating is limited. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Leslie Wheelock (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

In many instances, these resources allow for the timely evaluation of drug-related adverse events since data on healthcare utilized by a large number of individuals are readily available. However, because these data are typically collected for administrative purposes, information on

important health factors necessary to evaluate drug-outcome relationship may be absent or incomplete in these data sources. Examples include tobacco/smoking use and history, alcohol consumption, weight and height, patient and family medical history, or use of over-the-counter medications. Incomplete capture or the absence of this information can result in biased or uncertain estimates for the drug-outcome relationship of interest leading to inadequate evaluation of the safety profile of prescription drug products.

Webcast: Please be advised that as soon as possible after a Webcast of the public workshop is available, it will be accessible at:

<http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm429136.htm>.

Dated: April 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-08846 Filed: 4/16/2015 08:45 am; Publication Date: 4/17/2015]